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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,473	12/17/2003	Donald K. Jones	CRD5061	8194
27777	7590	10/19/2006	EXAMINER AHMED, AAMER S	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/738,473

**Applicant(s)**

JONES ET AL.

**Examiner**

Aamer S. Ahmed

**Art Unit**

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26, 27 and 29 is/are allowed.
- 6) ☒ Claim(s) 1-25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 14-17, and 19-21, 23-24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Guruwaiya et al U.S. Patent Number 6,251,136. Guruwaiya et al discloses an implantable device comprising a support member (16); a bioactive agent (20) on the support member (16); and an outer barrier (22) disposed on the bioactive agent (20), the outer barrier exhibiting the characteristic of being substantially inert to bodily fluid by dissolving when exposed to an external fluid agent, heat activating agent or laser and is comprised of ethylene vinyl alcohol (col. 4 line 32); (inherent since the barrier material is the same as the present invention ethylene vinyl alcohol so the claim is structurally met, the composition is met and the device of Guruwaiya et al is fully capable of the intended use); and wherein the bioactive agent (20) takes the form of a coating applied to the support member (see figure 2); and wherein the bioactive layer is integral with the support member (see figure 4); and wherein the outer barrier (22) takes the form of a coating applied to the bioactive agent (see figure 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guruwaiya et al in view of Eder et al U.S. Patent Number 5,980,550.

Guruwaiya et al U.S. Patent Number 6,251,136, discloses an implantable device comprising a support member (16); a bioactive agent (20) on the support member (16); and an outer barrier (22) disposed on the bioactive agent (20), the outer barrier exhibiting the characteristic of being substantially inert to bodily fluid by dissolving when exposed to an external fluid agent, heat activating agent or laser and is comprised of ethylene vinyl alcohol (col. 4 line 32); (inherent since the barrier material is the same as the present invention ethylene vinyl alcohol so the claim is structurally met, the composition is met and the device of Guruwaiya et al is fully capable of the intended use); and wherein the bioactive agent (20) takes the form of a coating applied to the support member (see figure 2); and wherein the bioactive layer is integral with the support member (see figure 4); and wherein the outer barrier (22) takes the form of a coating applied to the bioactive agent (see figure 2).

Furthermore, Guruwaiya discloses that “a variety of pharmacological agent are commercially available . . . examples of such agents include but are not limited to antibiotic, anti-thrombotic and anti-restenotic drugs . . .” (paragraph 19), but fails to explicitly disclose that the support member is a vascular occlusive helically wound metallic embolic coil nor that the bioactive coating is thrombus inducing.

Eder et al discloses a similar device in which the support member is a vascular occlusive helically wound metallic embolic coil nor that the bioactive coating is thrombus inducing (see figure 2 and col. 6 line 1).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the coatings of Guruwaiya with the embolic coil as taught by Eder et al in order to provide a more controlled bioactive implant.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guruwaiya et al in view of Snyder 5,658,308. Guruwaiya et discloses the device as described above in reference to claim 1, including the ethylene vinyl alcohol outer barrier coating (col. 4 line 32), (the external agent comprised of dimethyl sulfoxide is inherent since the barrier material is the same as the present invention ethylene vinyl alcohol so the claim is structurally met, the composition is met and the device of Guruwaiya et al is fully capable of the intended use). Guruwaiya fails to disclose that the bioactive agent is comprised of polyglycolic acid.

Snyder discloses a similar device in which the bioactive agent is polyglycolic acid (col. 2 line 44).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Guruwaiya et al by making the bioactive agent polyglycolic acid in order to increase thrombosis.

***Allowable Subject Matter***

Claims 26, 27 and 29 are allowed.

***Response to Arguments***

Applicant's arguments filed 08/07/2006 have been fully considered but they are not persuasive. Applicant argues that there combining the Guruwaiya et al and Eder references would destroy the intent and purpose of each of the references, however as discussed above Guruwaiya et al discloses that any agent may be used on the device (paragraph 19).

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

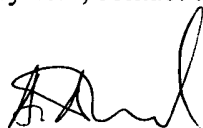
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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